510(K) Summary, K121632

AUG 10 2012

Simple Diagnostics®

11555 Heron Bay Blvd., Suite 200
Coral Springs, Florida 33076
☎ (877) 342-2385
Contact person: Muhammad Arif
Date prepared: May 22, 2012

1. Trade Name: Comfort EZ Pen Needle
Common Name: Pen Needle
Classification Name: Syringe, piston, product code FMI, Regulation: 880.5570
Class of device: Class II.

2. The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : Feel Fine insulin pen needle K080904 (Comfort EZ is a relabeled version of this product) as well as K100005 and K051899 Becton Dickenson Pen Needles.

3. Description of device: The Pen Needle consists of a sterile cap, needle cap needle hub, which can be fixed with needle and protected by blister paper. The sterile cap functions to maintain the sterility of the needle because sterile cap covers the needle hub and needle cap with blister paper sealed on the opening hole of sterile cap. The needle hub can be connected to the pen. The needle cap cover is intended to provide physical protection to the needle tube. They are supplied with a sterile fluid path, (EO), nontoxic, and non pyrogenic, for single use only, disposable. The devices operate on the principles of common piston syringes.

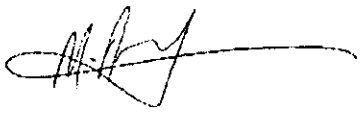
4. Intended use: These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes.

5. Technological characteristics: The Comfort EZ Pen Needles and the predicate devices have identical technological characteristics and perform the same way as common piston syringes. These syringes are EO sterilized. The sterility assurance level is 10^{-6} They are compatible with ISO "Type A" standard pens.

6. Performance: Bench tests were performed. Bench testing included biocompatibility, compatibility with ISO Type A pens, mechanical testing, sterility testing including EO residues. The tests demonstrated that the device is as safe, as effective, and performs in a substantially equivalent manner to the previous predicate devices. The Comfort EZ devices are relabeled versions of the Feel Fine (K080904) product. Predicate labeling (BD) was evaluated and found to be comparable to our current labeling.

Exhibit 6. Truthful and Accuracy Statement as required per 21CFR807.87(k).

I certify that, in my capacity as President of Simple Diagnostics, Inc. I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.



Muhammad Arif
March 1, 2012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Simple Diagnostics, Incorporated
C/O Mr. Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
8870 Ravello Court
Naples, Florida 34114

AUG 10 2012

Re: K121632
Trade/Device Name: Comfort EZ Pen Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 25, 2012
Received: June 12, 2012

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K12_____.

Device Name: Comfort EZ Pen Needle

Indications For Use:

These disposable sterile insulin pen needles are intended for subcutaneous injection of insulin in the treatment of diabetes

Prescription Use ____ AND/OR Over-The-Counter Use _X_.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

8/1/12

(Division Sign-Off)
vision of Anesthesiology, General Hospital
fection Control, Dental Devices

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